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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,339	03/12/2002	Peter Jungblut	028622-0108	1997

7590 10/12/2005  
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EXAMINER

SWARTZ, RODNEY P

ART UNIT PAPER NUMBER

1645

DATE MAILED: 10/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action  
Before the Filing of an Appeal Brief**

Application No.

09/890,339

Applicant(s)

JUNGBLUT ET AL.

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

1645

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 01 June 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☒ The Notice of Appeal was filed on 1 June 2005. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: none.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: 44, 45 and 48-68.  
Claim(s) withdrawn from consideration: 27-43, 48-50, 54-57, 64-68 drawn to protein.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_.  
13. ☐ Other: \_\_\_\_\_.



### **DETAILED ACTION**

1. Applicants' Response to Final Office Action, received 1 June 2005, is acknowledged, but will not be entered because it raises new issues.

Applicants' have requested that claims 44, 48, 50, 51, 52, 54, 55, 56, 57, 63, 64, 66, and 67 be amended and that claims 27-43 and 58-62 be canceled.

### **New Issues**

2. It is noted that in newly amended claim 44, line 9, immediately after inserted *M. tuberculosis* there is both a period and a comma, i.e., "*M. tuberculosis*," raising a new indefiniteness issue

3. It is noted that in newly amended claim 57, lines 1-2, the claim reads "detection of said component associated with Mycobacterium". Newly amended claim 56 from which it depends would not recite "component associated with Mycobacterium", but "component associated with *M. tuberculosis*" raising a new lack of antecedent issue.

### **Examiner's Observations**

4. In order to expedite the prosecution of this application, the examiner has considered applicants' amendments and arguments as if the Response were entered.

5. The rejection of claims 48-50 and 54-57 and now newly added claims 64, 65, , 67 and 68 under 35 U.S.C. 112, second paragraph, indefiniteness for being drawn to nonelected inventions, would have been withdrawn in light of the proposed amendments of the claims.

6. The rejection of claim 51 under 35 U.S.C. 112, second paragraph, indefinite for depending from a nonelected claim 27, would have been withdrawn in light of the proposed amendment of the claim.

Art Unit: 1645

7. The rejection of claims 58, and 62 under 35 U.S.C. 112, second paragraph, as being indefinite for identification of *M. tuberculosis* protein, would have been moot in light of the proposed cancelation of the claims.

8. The rejection of claims 44, 45, 48-50, and 52-56 under 35 U.S.C. 112, second paragraph, as being indefinite for identification of *M. tuberculosis* protein, would have been withdrawn in light of the proposed amendment of the claims.

9. The rejection of claims 44, 45, and 48-68 under 35 U.S.C. 112, first paragraph, scope of enablement for identification of proteins by comparison of any/all other virulent strains of *Mycobacterium* to any/all other avirulent strains of *Mycobacterium* would have been withdrawn in light of the proposed amendments of the claims.

#### **Rejections Maintained**

10. The rejection of claims 49, 51, 52, 54, 65, and 68 under 35 U.S.C. 112, first paragraph, scope of enablement for vaccines, would have been maintained for reasons of record.

Applicants argue that in light of the amendments of the claims which are now directed to Rv3407 and Rv0068 along with the earlier filed declaration of Prof. Kaufman, the rejection is obviated.

The examiner has considered applicants' argument, but would not find it persuasive concerning the use of "fragments" of whole Rv0068 and whole Rv3407. Neither the specification nor the declaration of Prof. Kaufman provide sufficient guidance/example for determining what are the critical "fragment(s)" of the whole molecule which must be retained for vaccine efficacy.

Art Unit: 1645

11. The rejection of claims 51 and 57 under 35 U.S.C. 112, second paragraph, as being indefinite for identification of *M. tuberculosis* protein, would have been maintained for reasons of record.

Applicants argue that the amendments of the claims obviates the rejection.

The examiner has considered applicants' argument, but would not find it persuasive.

The proposed amended claim 51 would remain drawn to a method for the production of a vaccine against a virulent strain of the "genus Mycobacterium" comprising the steps of recombinantly expressing a differentially expressed protein selected from a group consisting of *M. tuberculosis* proteins. It would remain unclear how one identifies a specific *M. tuberculosis* protein for use as a vaccine against any/all other species of the genus.

The proposed amended claim 57 would remain drawn to a method for detecting the presence of *M. tuberculosis* utilizing a component associated with "Mycobacterium", i.e., any/all species of the genus. It would remain unclear how one detects the presence of specific *M. tuberculosis* utilizing a component associated with any/all other species of the genus.

### **Conclusion**

12. Applicants' amendment of the claims is not entered because it would raise new issues.

13. Claims 44, 45, and 48-68 drawn solely to DNA remain finally rejected. Claims 27-43, 48-50, 54-57, and 64-68 drawn to other inventions remain withdrawn from consideration.

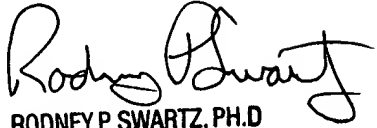
14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

Art Unit: 1645

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
RODNEY P SWARTZ, PH.D  
PRIMARY EXAMINER  
Art Unit 1645

October 5, 2005